CID 275

PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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605 Darling Street
BALMAIN NSW 2041

RECEIVED
9 JUN 2004
F. B. RICE & CO.

PCT

WRITTEN OPINION
(PCT Rule 66)

2 MAY 2005

Date of mailing *(day/month/year)*	08 JUN 2004
Applicant's or agent's file reference: 116757/REH/car	**REPLY DUE** within **TWO MONTHS** from the above date of mailing

International Application No.	International Filing Date *(day/month/year)*	Priority Date *(day/month/year)*
PCT/AU2003/001584	28 November 2003	29 November 2002

International Patent Classification (IPC) or both national classification and IPC
Int. Cl. [7] A61K 9/00, A61M 31/00, A61F 11/04, A61P 41/00

Applicant
COCHLEAR LIMITED et al

1. This written opinion is the **first** drawn by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:.

I	[X]	Basis of the opinion
II	[ ]	Priority
III	[ ]	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	[ ]	Lack of unity of invention
V	[X]	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	[ ]	Certain documents cited
VII	[ ]	Certain defects in the international application
VIII	[X]	Certain observations on the international application

3. The **FINAL DATE** by which the international preliminary examination report must be established according to Rule 69.2 is:
29 March 2005

4. The applicant is hereby **invited to reply** to this opinion.

When? See the **Reply Due** date indicated above. However, the Australian Patent Office will not establish the Report before the earlier of (i) a response being filed, or (ii) one month before the **Final Date** by which the international preliminary examination report must be established. The Report will take into account any response (including amendments) filed before the Report is established.
If no response is filed by 1 month before the Final Date, the international preliminary examination report will be established on the basis of this opinion.
Applicants wishing to have the benefit of a further opinion (if needed) before the report is established should ensure that a response is filed at least **3 months before the Final Date** by which the international preliminary examination report must be established.

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3.
For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4*bis*.
For an informal communication with the examiner, see Rule 66.6.

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WRITTEN OPINION

International application No.
PCT/AU2003/001584

I. Basis of the opinion

1. With regard to the **elements** of the international application:*

[X] the international application as originally filed.

[ ] the description, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of

[ ] the claims, pages , as originally filed,
pages , as amended under Article 19,
pages , filed with the demand,
pages , received on with the letter of

[ ] the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of

[ ] the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

[ ] contained in the international application in printed form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. [ ] The amendments have resulted in the cancellation of:

[ ] the description, pages

[ ] the claims, Nos.

[ ] the drawings, sheets/fig.

5. [ ] This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"*

WRITTEN OPINION

International application No.
PCT/AU2003/001584

V. **Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims **7, 12 to 19 and 38 to 50**	**YES**
	Claims **1 to 6, 8 to 11 and 20 to 37**	**NO**
Inventive step (IS)	Claims **nil**	**YES**
	Claims **1 to 50**	**NO**
Industrial applicability (IA)	Claims **1 to 50**	**YES**
	Claims **nil**	**NO**

2. Citations and explanations

D1. WO 02/041666 A1 (Cochlear Limited) 23 May 2002. See in particular page 17 line 20 to page 18 line 10 and the claims.

D3. WO 03/072193 A1 (Cochlear Limited) 4 September 2003. See especially page 4 line 31 to page 6 line 2 and the claims.

D4. WO 01/041674 A1 (Lahtinen, Mika) 14 June 2001. See the whole document in particular page 7 line 36 to page 9 line 9, the examples and claims

D5. WO 00/057949 A1 (Cardiac Pacemakers, Inc) 5 October 2000. See the claims.

D7. US 6,038,482 (David J. Vachon) 14 March 2000. See the abstract, column 3 lines 15 to 48, the drawings, example and claims.

D8. US 6,309,410 B1 (Janusz A. Kuzma et al) 30 October 2001. See the abstract, column 3 line 50 to column 5 line 60, the drawings and claims.

D9. US 6,304,787 B1 (Janusz A. Kuzma et al) 16 October 2001. See the abstract, column 4 lines 1 to 27, the drawings and claims.

D10. WO 02/083234 A1 (St. Jude Medical AB) 24 October 2002. See page 4 line 6 to page 7 line 10, the drawings and claims.

D1 and D3 disclose cochlear implants with provision for drug delivery to the cochlea. They do not disclose details of the location of the bioactive substances nor of the arrangement of the pores in a drug retaining substrate. Claims 1 to 6, 13 and 20 to 37 are not novel in comparison.

D4 discloses coating of implanted devices with nucleic acids which encode materials that improve biocompatibility. The nucleic acids may be held in porous, biodegradable or biocompatible materials including metals and polymers. The present claims are novel in comparison but when D4 is taken in combination with any or all of D1, D2, D3 and D6 claims 1 to 50 lack an inventive step.

D5 discloses cardiac pacemaker leads and electrodes with porous substrates carrying drugs. Claims 1, 2, 5, 8 to 11, 20, 22, 24 to 26, 28, 29 and 31 to 35 are not novel in comparison and when D5 is taken in combination with any or all of D1 and D3 claims 1 to 50 lack an inventive step.

WRITTEN OPINION

International application No.
PCT/AU2003/001584

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date (valid claim) *(day/month/year)*
WO 03/049658 A1	19/6/2003	10/12/2002	10/12/2001

D6 discloses cochlear implants with provision for drug delivery to the cochlea. It does not disclose details of the location of the bioactive substances nor of the arrangement of the pores in a drug retaining substrate.

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure *(day/month/year)*	Date of written disclosure referring to non-written disclosure *(day/month/year)*

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1 to 5, 7 to 22, 24 to 26, 28 to 29, 31 to 35, 37, 38, 44 to 48 and 50 do not, or do not necessarily define a cochlear implant that incorporates a porous biocompatible material having a bioactive substance disposed therein. These claims define a wide variety of implantable devices which do not necessarily incorporate electrode assemblies and are not fully supported by the description which describes a cochlear implant..

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box V

D7 discloses a cardiac pacemaker lead and electrode which contains a matrix loaded with a drug. Claims 1, 2, 5, 8 to 11, 20, 22, 24 to 26, 28, 29 and 31 to 35 are not novel in comparison and when D7 is taken in combination with any or both of D1 and D3 claims 1 to 50 lack an inventive step.

D8 discloses a cochlear implant with a drug delivery channel through the centre, while in D9 a cochlear implant may be coated with a drug or have a drug delivery channel as in D8. Claims 24, 26, and 27 are not novel in comparison.

D10 discloses a cardiac pacemaker lead and electrode which contains a matrix loaded with a drug. Claims 1, 2, 5, 8 to 11, 20, 22, 24 to 26, 28, 29 and 31 to 35 are not novel in comparison and when D10 is taken in combination with any or both of D1 and D3, claims 1 to 50 lack an inventive step.